

## REMARKS

Claims 1, 8, 10-12, 14-18, 43, and 51-65 are pending in the application. Reconsideration and allowance of the above-referenced application are respectfully requested. Applicants petition for a one month extension of time to reply to the office action mailed March 25, 2008.

Claims 51 and 52 stand objected under 37 CFR 1.75. Applicants have amended claim 51 and 52 to overcome the objection. Reconsideration and withdrawal of the objection is respectfully requested.

Claims 1, 8, 10, 12, 14-18, and 62-65 stand rejected under 35 USC 103(a) as being unpatentable over Oz (U.S. Patent No. 6269819) in view of Kuehn (U.S. Patent No. 6165183). Applicants respectfully traverse the rejection because the teachings of the cited references are both restricted to providing a structure on the leaflets and, moreover, neither reference discloses or suggests providing a structure directly on the valve annulus.

All of the rejected claims recite a feature wherein the supporting structure is adapted for deployment directly on the annulus rather than on leaflets connected to the annulus.

The Office Action ignores the above-emphasized limitation regarding deployment directly on the annulus. The Office Action makes reference to various portions of Oz; however, rather than support the rejection, each of the cited portions of Oz is explicitly limited to devices which act directly on the leaflets. By manner of example, the rejection references col. 2, lines 33-53:

The present invention is directed to a method and apparatus for use in heart valve repair involving the use of an inserted device or grasper for grabbing and clamping together the anterior and posterior leaflets of the valve, by insertion into the left ventricle through the right chest via a thoroscope, through the jugular vein, or through the femoral artery. The grasper will grab both leaflets, preferably after the heart has been stopped or slowed pharmacologically.

The correctness of the initial grasp is assessed by, for example, intraoperative echocardiography, to ensure, for example, in the case of the mitral valve, that the mitral regurgitation is resolved. If not, the grasper will be able to "adjust" the leaflets to allow better coaptation or, if needed, re-grab the leaflets in a different location.

Either inherent to the grasper, as an integrally attached component or as a separate device, a fastening device is introduced and a fastener is deployed to securely hold the leaflets in place after the grasper has been released. The remaining portion of the device, or optionally any separate device, is then removed.

The rejection further references col. 5, lines 36-45:

FIG. 10 is a schematic representation of a cross section of the adjustable grasper depicted in FIG. 9. The jaws comprise grasper surfaces 58, an upper anvil 62 with recess 71, and a lower anvil 64 within which is located a staple type fastener 66 to effect the fastening of valve leaflets.

Oz teaches a completely different approach to treating mitral valve reflux; namely, an approach in which the leaflets are fastened to each other (edge-to edge). The Oz device is specifically engineered to achieve the leaflet fastening approach. Even if one of ordinary skill were motivated to practice the approach Applicants have disclosed and claimed, the Oz device could not be utilized. The Oz device is not adapted to deploy a support structure directly on the annulus, and the modifications necessary to adapt a device according to Oz to one adapted to deploy a support structure directly on the annulus would not have been obvious to one of ordinary skill in the art at the time of the invention. Making a device for percutaneous delivery of a structure is a *significant* feat of engineering. There is a difference between having a desire to perform percutaneous surgery and actually disclosing a device capable of doing it.

Like Oz, Kuehn's disclosure is restricted to various devices and methods for acting on the leaflets directly – not on the annulus. In paragraph 4, the Office Action states that claims 1, 8, 10, 12, 14-18, and 62-65 are rejected under 35 U.S.C. 103 as being unpatentable over Oz in view

of Kuehn. However, the Office Action makes no further reference to Kuehn in support of the rejection under 35 U.S.C. 103. The Examiner has not explained how the rejection is supported by Kuehn's disclosure. Without any explanation by the examiner, Applicants are left to determine how the combination of Oz and Kuehn result in the claimed invention. Applicants have reviewed Kuehn's disclosure in detail and neither the drawings nor the written description discloses or suggests a supporting structure adapted for deployment directly on the annulus as recited in the claims.

Kuehn discloses a large number of different embodiments, all of which are purportedly adapted for affixing one leaflet to the other. None of the embodiments is capable of deployment directly on the annulus, a feature of the claimed invention. Applicants respectfully reiterate that the rejection combines references whose teachings cannot be reconciled.

Kuehn discloses various embodiments which relate thematically to suturing or clipping leaflets. Even with respect to leaflet suturing Kuehn's disclosure is lacking because none of the embodiments are actually enabled. For example, Fig. 4 shows a needle 130 which is supposedly used to pass suture into the edge of the leaflets. FIG. 3 shows leaflets 122, 124 with suture 120. However, nowhere in Kuehn is there an explanation of how the leaflets were captured and restrained while the needle 130 is pierced therethrough. Fig. 5 shows another suturing device which purportedly may be used to suture the leaflets 122, 124 but again there is no enabling substance to the disclosure apart from the drawing. Fig. 6 shows a cutter used to cut the suture line. Unfortunately, Kuehn doesn't disclose how to find the suture with cutter or what happens to the ends of the suture which are cut. FIG. 8 shows a barbed pitch 206 and Fig. 12 shows the

pitch with its barbs piercing the leaflets 122, 124 – however, there is no device for delivering the barb nor is there any means for restraining the leaflets while they are harpooned.

Kuehn does not disclose that it is well known to percutaneously deliver anchors. Rather, Kuehn discloses a series of unsupported and unenabled hopes and aspirations. Applicants respectfully assert that it is improper for the Examiner to rely on Kuehn as emblematic of the level of skill in the art because Kuehn fails to disclose or suggest an actual working embodiment.

The Examiner has not fulfilled the statutory burden of demonstrating *prima facie* obviousness because neither of the cited references discloses a supporting structure adapted for deployment directly on the annulus rather than on leaflets connected to the annulus, a feature of the rejected claims. In support of the foregoing, Applicant will provide at a later date a Declaration of Troy L. Thornton under 37 C.F.R. §1.132.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 11 stands rejected under 35 USC 103(a) as being unpatentable over Oz as applied to claim 1, in further view of O'Connor (US 5450860).

Applicants repeat herein the reasons provided above in traversing the rejection of claim 1 over Oz.

O'Connor discloses a conventional open-heart annuloplasty procedure. O'Connor explicitly teaches that the mitral valve is exposed by left atriotomy. See col. 8, lines 44-51. Both the methods and devices disclosed in O'Connor are restricted to non-catheter based procedures in which the mitral valve is exposed.

Even if one of ordinary skill in the art were motivated to combine the teachings of Oz and O'Connor, it would not be possible to modify a device according to Oz which as adapted to act on the valves to perform the method disclosed by O'Connor. Even assuming, *arguendo*, that it would be possible to modify Oz to act on the annulus, such modification would necessarily be non-obvious. The Examiner underestimates the technical difficulties which must be overcome in designing an endovascular device. Simply having the aspiration to create an endovascular treatment device is not sufficient. The modifications necessary to adapt Oz to perform the method disclosed by O'Connor are non-obvious and well beyond the level of skill of one of ordinary skill in the art at the time of the invention. In support of the foregoing, Applicant will provide at a later date a Declaration of Troy L. Thornton under 37 C.F.R. §1.132.

Claims 43, 51, and 53-61 stand rejected under 35 USC 103(a) as being unpatentable over Northrup (US 5593424) in further view of Kuehn (US 6165183).

Applicants respectfully repeat herein the arguments provided above in traversing the rejection over Kuehn; namely, that Kuehn does not represent the state of the art at the time of the invention and does not disclose or enable a device which is capable of percutaneously delivering anchors directly on the annulus as recited in the rejected claims.

Northrup discloses an apparatus comprising a plurality of suture support segments 10 which are connected by sutures 60. However, a device according to Northrup is not adapted for catheter-based (percutaneous) delivery, a feature of the rejected claims. Northrup does not explicitly teach an open-heart procedure. However, in the absence of a device for delivering the segments 10 the reader is left to imagine an open-heart procedure which would not require a specialized device.

Accordingly, the combination of Northrup and Kuehn does not disclose or suggest the claimed invention.

For at least these reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 43, 51, and 53-61.

Claim 52 stands rejected under 35 USC 103(a) as being unpatentable over Northrup in view of Kuehn as applied to claim 43, in further view of Oz (US. 6,269,819). Applicants respectfully traverse as follows.

As a preliminary matter, Applicants repeat herein the arguments provided above in traversing the rejection of claim 43. Like Kuehn, Oz discloses various embodiments used to attach the leaflets. Neither Kuehn nor Oz disclose or suggest a device or method for suitable for placing anchors directly on the annulus – instead both disclose and teach acting directly on the leaflets. Northrup discloses a method which cannot be performed by Kuehn or Oz. Consequently, the combination fails to disclose the percutaneous attachment of staples directly on the annulus, a feature of the claimed invention. For at least this reason, Applicants respectfully request that the rejection of claim 52 be reconsidered and withdrawn.

#### **New Claim**

Claim 66 is new. Applicants respectfully submit that the subject matter of claim 66 is not taught or suggested by any of the cited art.

#### **Conclusion**

The above is believed to be a complete response. In view of the amendments and remarks herein, Applicants believe that all claims are now in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken

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by the Examiner are not to be construed as acquiescence with other positions of the Examiner that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims. The Examiner is invited to telephone the undersigned to resolve any remaining issues and/or informalities and expedite prosecution of this case.

Please apply any charges or credits to Deposit Account No. 50-0311.

Respectfully submitted,

Date: July 25, 2008

  
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